Veterinary Medicines Directorate

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Post Authorisation Assessments

Ovivac P Plus Suspension for Injection for Sheep

Vm 06376/4119

7 August 2026	Addition of MSD AH Danube Biotech GmbH, Krems, Austria as blending and filling site for the finished product. Addition of Intervet International B.V., Boxmeer, NL as an alternative potency testing site for the Chauvoei blend. Deletion of the sterility test on the vaccine base. Changes on the vaccine base preparation: add the possibility to use non-heated water for injections and shorten the sterilisation time. Continuous stirring to be performed until the end of the filling process to ensure homogeneity of the bulk vaccine. Add the possibility to use 10% w/v thiomersal solution to achieve the final thiomersal concentration in the vaccine bulk. Increase in maximum batch size to 5000 L for the finished product. Deletion of the backup test for endotoxin testing, since this test has never been used and will never be used for 3R reasons.
01 March 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
17 November 2025	To change the shape and dimensions of the packaging material and to use an alternative rubber stopper. To add a step for centrifugation to the in-process control test for formaldehyde for M. haemolytica. To add a step for centrifugation to the in-process control test for formaldehyde for P. trehalosi. To add an alternative in-process test for sterility for M. haemolytica. To add an alternative in-process test for sterility for P. trehalosi. To remove the in-process test for specific gravity for M. haemolytica. To remove the in-process test for specific gravity for P. trehalosi. To change the volume of inoculum media, update the period of storage for the inactivated antigen and include an additional method of storage for the inoculum media for M. haemolytica. To change the volume of inoculum media, update the period of storage for the inactivated antigen and include an additional method of storage for the inoculum media for P. trehalosi. To add an additional site for antigen manufacturing and quality control testing for M. haemolytic. To add an additional site for antigen manufacturing and quality control testing for P. trehalosi.
22 September 2025	One-off alignment of the product information with version 3 of the SPC and QRD templates.

13 March 2025	Deletion of a manufacturing site for an active substance.
18 November 2024	Change in legal entity of MA holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands.
02 October 2024	Change in test procedure for active substance. Change in test procedure for the finished product.
01 November 2023	Change to comply with Ph. Eur.
27 June 2023	To update of the sterility test procedure performed on the finished product according to Ph.Eur. 2.6.1. Minor adjustments to the method suitability test to improve recovery of the A. brasiliensis reference strain.
17 March 2023	To optimise the statistical analysis method for the Fab ELISA to confirm M.haemolytica identity and P. trehalosi identity/potency. To add Intervet International B.V., Boxmeer, NL, as finished product Quality Control test site.
23 February 2023	Addition of an in vitro toxicity test for C. chauvoei cells and toxoid. Addition of the use of bovine liver extract in Clostridia growth medium.
11 August 2022	Change in test procedure for the finished product.
31 May 2022	Change of a test procedure for the active substance. Change of a test procedure for the active substance.
12 January 2022	Changes to a test procedure for the active substance. Change(s) in the manufacturing process of the active substance. Change(s) in the manufacturing process of the active substance. Change(s) in the manufacturing process of the active substance. Change(s) in the manufacturing process of the active substance. Change(s) in the manufacturing process of the active substance. Change(s) in the manufacturing process of the active substance.
05 October 2021	Update of the test procedure to comply with the updated general Ph. Eur monograph. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Addition of a site where batch control/testing takes place.
17 March 2021	Change in the manufacturing process of the finished product.
01 October 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
11 September 2020	Change in the name of a manufacturer used in the manufacture of the active substance.
02 June 2020	Change in the name of the MAH, from Intervet UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
01 April 2019	Addition of a manufacturer responsible for batch release of the finished product.

18 May 2018	Change in the manufacturing process of the active substance. Change in the manufacturing process of the active substance.
30 March 2017	Change in name of a manufacturer of the active substance.
29 May 2015	Change in specification parameter of the finished product.
19 July 2013	Change in the manufacturing process of the active substance, change to in-process controls of the active substance.
22 March 2012	Change to the manufacturer of the finished product.
11 May 2011	Update to Part II dossier
08 July 2009	Addition of a manufacturer of the finished product with a consequential change to the shape of the stopper.
15 April 2008	Changes to the SPC and product literature to bring them in line with new legislation.
15 April 2008	Change in legal category from PML to POM-VPS.
01 June 2006	Renewal
05 October 2005	Change to comply with supplements to the pharmacopoeias.
20 June 2005	Change of distributor.
21 January 2005	Change to the in-process controls for the finished product.
22 November 2002	Change to comply with Ph.Eur. monograph.
04 October 2002	Change in the shape of the packaging.
04 October 2002	Change of sites of assembly and batch release.
21 February 2002	Renewal
09 November 2001	Change to supplier of an ingredient.
31 August 2001	Addition of a distributor.
13 June 2001	Change to the manufacturing process.
15 September 2000	Change to Quality Control procedures.
30 August 2000	Addition of a manufacture of the active substance.
06 June 2000	Extension of shelf life to 36 months.
29 March 2000	Change in specification of the active substance.
21 March 2000	Change in name of MAH.
22 December 1999	Change in batch size of the active substance.
08 November 1999	Addition of a preservative.
14 June 1999	Change in specification of an ingredient.
20 October 1998	Addition of a manufacturer.